

**REMARKS**

Claims 16-23 are pending. Claims 24-30 have been withdrawn pursuant to a restriction requirement.

**Rejection under 35 U.S.C. § 103(a)**

Claims 16-23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over US 2002/0082687 (Moe).

In making the rejection, the Examiner concedes that “Moe fails to teach specifically a shape defined by a parabola in the x-y direction and a parabola in the z direction” as recited in claim 16, from which claims 17-23 depend. Therefore, the Examiner relies solely on the proposition that changes in size and shape amount to nothing more than a design choice, citing MPEP § 2144.04 IV(A)-(C); *In re Dailey*, 357 F.2d 669 (CCPA 1966); and *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), but without offering any explanation why that should be the case.

Note that the Examiner cites other references that are not particular relevant here. *See In re Rose*, 220 F.2d 459 (CCPA 1955) (holding unpatentable a claimed device differing solely in size and weight from the prior art); *In re Rinehart*, 531 F.2d 1048 (CCPA 1976) (holding unpatentable “mere scaling up of a prior art process”).

**The Examiner Has Failed to Set Forth a Prima Facie Case of Obviousness**

Applicants respectfully submit that the Examiner has misapplied the case law and the guidance of MPEP § 2144.04 IV. In particular, *In re Dailey* stands for the proposition that a rejection cannot be premised on notion of design choice when “the particular configuration [of the article] is significant” and is something “more than one of numerous configurations a person of ordinary skill would find obvious for the purpose.” 357 F.2d at 672-73. Further *Gardner* stands for the proposition that a claim reciting relative dimensions of an article is only patentable if it “specif[ies] a device which perform[s] and operate[s] any differently from the prior art.” 725 F.2d at 1349.

Numerous cases in the Board of Patent Appeals and Interferences have required the Examiner do more than provide a naked citation of the propositions of MPEP § 2144.04

IV(A)-(C), *In re Dailey*, 357 F.2d 669 (CCPA 1966), *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), and the like.

In *Ex parte Jeffery Moore*, Appeal No. 96-2852 (BPAI), the Board overturned the rejection of a claim to a chalk box reciting a particularly shaped arched neck, holding that “the shape of the neck . . . is significant in that it solves a stated problem” and therefore “the shape of the neck cannot be baldly dismissed as an obvious matter of design choice.” 1996 WL 1796237 at \*2.

In *Ex parte Joel L. Sereboff*, Appeal No. 2004-2354 (BPAI), the Board overturned the rejection of a claim to a trauma mitigation device having a crushable matrix including “pyramids which are disposed in pairs connected at the apexes” over prior art disclosing “a plurality of hemispheres disposed in pairs connected at the convexities.” In doing so, the Board noted that “[c]onspicuously missing from the examiner’s analysis . . . is any explanation as to how (and why) one of ordinary skill in the art would have modified” the prior art references to obtain the claimed invention. 2005 WL 951669 at \*7. A claim cannot be held obvious on these grounds when “the examiner has not discharged the burden of developing, *prima facie*, a persuasive rationale, based on evidence of record that would have led one of ordinary skill in the art to the claimed subject matter from” the teachings of the prior art. *Id.*

Similarly, in *Ex parte Hall Virgil Jr.*, Appeal No. 1996-1049 (BPAI), the Board overturned the rejection of a claim to a device having “a cylindrical bore which allows for a threaded fastener to be used rather than [the prior art device’s] square or rectangular fastener which is pushed into the female connector.” 2001 WL 1057294 at \*3. The Board opined that “[t]he examiner provides no reasoning as to why one of ordinary skill in the art would have considered the difference between [the prior art] configuration and [the claimed] arcuate configuration to be insignificant such that [the prior art] configuration would have fairly suggested [the claimed configuration] to one of ordinary skill in the art.” *Id.*

Importantly, an examiner is still required to support a *prima facie* case of obviousness when rejecting a claim that recites a change of shape compared with the prior art, notwithstanding changes in patent law jurisprudence since the above cases were decided. In particular, in *Ex parte Jiri Pazdirek*, Appeal No. 2007-1914 (BPAI), the Board declined to sustain a rejection of a claim to a link assembly for a vehicle suspension system having a

sleeve nut including a “cup-shaped head” and a grommet including “a curved surface at one end complementary in shape to the cup-shaped head” over a prior art assembly having a sleeve nut and a grommet not including those features. In doing so, the Board stated that “the Examiner points to no interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; or the background knowledge possessed by a person having ordinary skill in the art, as support for his conclusion that there existed at the time of the invention an apparent reason to modify [the prior art device] in the manner claimed.” 2007 WL 2745845 at \*4. For this proposition, the Board cited *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct 1727, 1740-41 (2007) and *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by merely conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”).

The Shape of Claimed Valve Leaflet is Significant and Causes the Valve to Perform Differently From Prior Art Valves

As in the above-cited cases, the shape of the leaflets in the claimed valve meets the tests set forth in *re Dailey* and *Gardner* and articulated in MPEP § 2144.04 IV. Indeed, the claimed leaflet shape is significant, and specifies a device which performs differently from the prior art devices of Moe and others, because the claimed leaflet shape results in reduced stresses and pressure gradients in comparison to previously shaped leaflets of heart valves. As a result, the life span of the heart valve in the claimed invention is increased.

The advantages of the claimed shape are made clear throughout the specification and figures of the present application. In particular, the claimed shape reduces the stress and strain on the leaflets so as to prolong the operating life of the valve. See, for example:

Page 5, lines 5-9: “The present inventor have [sic] surprisingly found that, by using leaflets with parabolic configuration in cross section, stresses of the leaflets can be reduced and hence the lifespan of the valve may be improved.”

Page 14, lines 4-7: “The inventor has surprisingly shown that by making the free edge of valve leaflets parabolic, the stress and strain characteristics of the leaflet at the free edge are improved.”

Page 37, lines 9-16: “In contrast to previous designs and teaching concerning valve construction, which was driven by the supposed need to obtain a close fitting seal of the leaflets, particularly at the free edge, the leaflets of the valves of the present invention were designed to minimise the stress experienced by the leaflet during cycling between the open and closed position.”

Page 37, lines 18-25: “To reduce the sharp curvature, which promotes stress points at specific points along the free edge, the length of the free edge (XY) of the leaflet was determined using a parabolic function. The parabolic length of the free edge can be determined by using the distances between the posts of the frame where the free edge is conjoined to the posts and the parabolic maximum.”

Page 39, lines 9-14: “By determining the lengths XY of the leaflet as a parabolic function or the like at each point in Z, such that the XY lengths in Z vary as a continuous function, localised stress concentrations can be minimised and a more uniform stress distribution across the leaflet achieved.”

Page 49, line 20 – page 50, line 3 (comparing the stress and strain on prior art valve leaflets as shown in FIGS. 8a, 8b, 8c, and 8d, with that on valves of the present invention as shown in FIGS. 9a, 9b, 9c, and 9d): “In addition to the above, it has also been determined that stress at the free edge of the leaflet, as shown in FIG. 8a, can be further reduced by trimming the free edge 34 of the leaflet in the longitudinal direction (Z) such that the free edge is substantially parabolic 70, with the maximum depth of the parabola being furthest from the notional untrimmed free edge 74. The maximum depth of the parabola is generally located at the midpoint of the free edge 72 (FIG. 9a). FIG. 9a shows the effect of introducing a parabolic curve in the vertical direction of the free edge. Comparison of FIGS. 8b, 8c and 8d with 9b, 9c and 9d shows that the strain energy release at the free edge is significantly reduced through the introduction of the parabola in the longitudinal direction (Z).”

Additionally, the claimed shape reduces the pressure gradient required to open the valve from a closed position. See, for example:

Page 60, lines 21-27: “As shown in FIG. 13, surprisingly, in addition to reducing the lateral stress of the valve, determination of the length of the leaflet at each point in Z according to a parabolic function not only minimises the formation of a belly in the leaflet, but also reduces the pressure gradient required to open the valve from a closed position.”

**Conclusion**

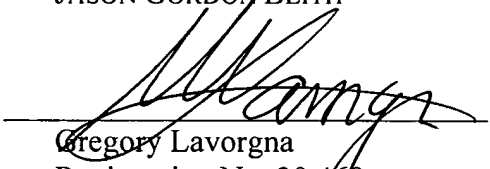
Therefore, in view of the foregoing, Applicants respectfully submit that the Examiner has not set forth a prima facie case of obviousness. Moreover, Applicants further respectfully submit that the claimed valve leaflet shape is not a mere design choice because the leaflet shape provides significant advantages over prior art devices, including a reduction of stress that prolongs valve life and a reduction in the pressure gradient that improves valve operation, all of which are set forth in the specification and none of which have been refuted by the Examiner.

Accordingly, withdrawal of the rejections, and an early notice of allowance of claims 16-23, is earnestly solicited.

Respectfully submitted,

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